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10/762,563	01/23/2004	Ralf-Peter Peters	A-8890.RNOMP / sbs	3199

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,563	Applicant(s) PETERS ET AL.	
	Examiner Brian J. Sines	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/19/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the amended claims have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Newly submitted claims 25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are directed to related microfluidic devices. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. For example, the microfluidic device of claim 25 specifically requires the incorporation of a sample carrier and a cover, such as a film or foil.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25 and 26 are withdrawn from consideration as being

directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the structure of the microfluidic channel arrangement that in part affects capillarity to induce liquid movement within the claimed device is unclear. Capillarity is the interaction between a liquid and the solid surface that is in contact with the liquid. In this case, capillarity or capillary forces would be affected by both channel structure, e.g., channel width or surface properties, and the properties, e.g., viscosity, of the liquid flowing through the channel. For example, do the channels have a specific size dimension, such as a channel width, or surface coating, that enables the claimed device to function as claimed? The liquid is not considered a positively recited structure of the claimed device. In claims drawn to an apparatus statutory class of invention, the structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device (see MPEP § 2172.01). Furthermore, a feature that is taught as critical in the specification should be recited in the claims (see MPEP § 2164.08c).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 11, 20 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Seki et al. (U.S. Pat. Appl. Pub. No. US 2002/0195463) (“Seki”).

Regarding claims 1 – 11, 20 and 23, Seki anticipates a microfluidic apparatus structure comprising: a first channel, e.g., 21, and one second channel, e.g., 23; the first channel has one inlet and one outlet; near the outlet, the structure inherently has a capillarity that is greater than or equal to the capillarity in near the inlet; the second channel branches off from the first channel at a branched connection point; the second channel inherently having a greater capillarity than the first channel at the branched connection point (see, e.g., paragraphs 84 – 97, 103 – 108 and 158 – 160; figures 5a – 5c). Seki anticipates the hydrophilic surface treatments at the transitions between channels that would inherently affect capillarity (see, e.g., paragraphs 80 and 81). Seki anticipates the changing of the geometrical properties, e.g., channel cross-section, that would change the capillarity effects and therefore control fluid flow through the device (see, e.g., paragraphs 84 – 96). Seki anticipates the incorporation of two channel systems (see, e.g., paragraphs 20 – 26). Seki anticipates the further incorporation of a microfluidic arrangement comprising sequential channel branch points (see, e.g., figures 7, 10 and 11). Apparatus claims

must be structurally distinguishable from the prior art in terms of structure, not function. The manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim (see MPEP § 2114 & § 2173.05(g)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1 – 11, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seki et al. (U.S. Pat. Appl. Pub. No. US 2002/0195463) (“Seki”).

Regarding claims 1 – 11, 20 and 23, Seki teaches a microfluidic apparatus structure comprising: a first channel, e.g., 21, and one second channel, e.g., 23; the first channel has one inlet and one outlet; near the outlet, the structure inherently has a capillarity that is greater than or equal to the capillary in near the inlet; the second channel branches off from the first channel at a branched connection point; the second channel inherently having a greater capillary than the

first channel at the branched connection point (see, e.g., paragraphs 84 – 97, 103 – 108 and 158 – 160; figures 5a – 5c).

Alternatively, Seki does not specifically teach the microfluidic channel configuration comprising first and second channels having specific capillarity or capillary force-inducing properties to facilitate controlled liquid flow within the device.

The applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). In this regard, Seki teaches hydrophilic surface treatments at the transitions between channels that would inherently affect the capillarity within each of the channels (see, e.g., paragraphs 80 and 81). Seki teaches changing of the geometrical properties, e.g., channel cross-section, that would change the capillarity effects and therefore control fluid flow through the device (see, e.g., paragraphs 84 – 96). Consequently, the capillarity properties of the channel structures of the device are considered an inherent property of the device that would affect fluid flow within the device. Seki teaches the incorporation of two channel systems (see, e.g.,

paragraphs 20 – 26). Seki teaches the further incorporation of a microfluidic arrangement comprising sequential channel branch points (see, e.g., figures 7, 10 and 11). Seki does teach the desirability of controlled liquid flow within the device using a channel configuration comprising a plurality of connected channels (see, e.g., paragraphs 18 – 32). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a microfluidic channel configuration comprising first and second channels having specific capillarity or capillary force-inducing properties to facilitate controlled liquid flow within the device.

2. Claims 12 – 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seki in view of Kellogg et al. (U.S. Pat. No. 6,063,589 A) (“Kellogg”).

Regarding claims 12 – 18, Seki does not specifically teach the incorporation of a stopping means, such as a capillary stop or microvalve, for controlling fluid flow within the disclosed device. Seki does teach the desirability of controlled liquid flow within the device using a channel configuration comprising a plurality of connected channels (see, e.g., paragraphs 18 – 32). The incorporation of various stopping means, such as capillary stops and microvalves, for providing fluid flow control within microfluidic devices are well known in the art. For example, Kellogg teaches the incorporation of a capillary stop, barrier or junction, and including valves, within a microfluidic device for facilitating fluid control within the device (see, e.g., col. 5, line 51 – col. 6, lines 66; col. 22, lines 17 – 63; col. 47, lines 8 – 61; figures 15A – 15D; 21A – 21E). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a stopping means as claimed with the disclosed microfluidic device for facilitating effective fluid flow control within the device.

Regarding claim 22, Seki does not specifically teach the incorporation of an aeration or vent channel within the disclosed device. Aeration or vent channels are common features of microfluidic devices that permit fluid flow within the device that are well known in the art. For example, Kellogg does teach the incorporation of aeration, vent or air displacement channels within microfluidic devices (see, e.g., col. 6, lines 7 – 13). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of an aeration channel within the disclosed microfluidic device to facilitate effective fluid flow.

3. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seki in view of Fuhr et al. (U.S. Pat. No. 6,465,225 B1) (“Fuhr”).

Regarding claim 19, Seki does not specifically teach the incorporation of a meander-shaped channel system structure. However, the incorporation of meander-shaped microchannel structures within microfluidic devices for facilitating sample processing and analysis is well known in the art. For example, Fuhr teaches the incorporation of a meander-shaped channel structure within a microfluidic device for facilitating sample processing (see, e.g., col. 6, lines 44 – 65). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a meander-shaped channel system structure as claimed with the disclosed microfluidic device for facilitating effective sample processing.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seki in view of Boschetti et al. (U.S. Pat. No. 7,144,743 B2) (“Boschetti”).

Regarding claim 21, Seki does not specifically teach the incorporation of an adsorbent material within the disclosed device. Seki does teach that a reagent 300 is positioned within the channel structure of the device for facilitating glucose analysis (see, e.g., paragraph 135; figure

10(d)). The utilization of adsorbents for carrying reagents within analytical microfluidic devices for testing is well known in the art. For example, Boschetti teaches the use of absorbents with analytical microfluidic biochip devices for facilitating sample analysis (see, e.g., col. 5, lines 15 – 36). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate and absorbent material as claimed with the disclosed microfluidic device for enabling effective sample processing and analysis.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

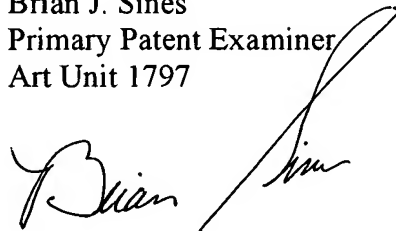
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Patent Examiner
Art Unit 1797

A handwritten signature in black ink, appearing to read "Brian Sines", is written over the printed name and title.